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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,959	08/10/2005	David Lovejoy	2223-189	2108

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MCCARTHY TETRAULT LLP
BOX 48, SUITE 4700,
66WELLINGTON STREET WEST
TORONTO, ON M5K 1E6
CANADA

EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1649	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,959	LOVEJOY ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-3, 5, 8-10, 48 and 50-52 are objected to as reciting an improper Markush Group. MPEP 803.02 states:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicant is advised that claims 1, 3, and 8 are each improper Markush claims because the plurality of nucleic acid and amino acid sequences recited in these claims lack a common utility which is based upon a shared structural feature lacking from the prior art.

Each of these proteins and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins or nucleic acids. Therefore, Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1 to 43. Claims 1-7 and 34, in so far as they are drawn to **any one** of the forty-three isolated nucleic acid sequences recited therein, classified in class 435, subclass 69.1, for example. For examples, the Invention of Group 1 consists of claims 1-7 and 34, only in so far as they encompass an isolated polynucleotide of SEQ ID NO: 18; the Invention of Group 43 consists of claims 1-7 and 34, only in so far as they encompass an isolated polynucleotide of SEQ ID NO: 100.

Groups 44-67, claim(s) 8-10, in so far as they are drawn to **any one** of the twenty-four isolated polypeptides recited therein, classified in class 530, subclass 324, for example. For examples, the Invention of Group 44 consists of claims 8-10, only in so far as they encompass an isolated polypeptide of SEQ ID NO: 13; the Invention of Group 67 consists of claims 8-10 only in so far as they encompass an isolated polypeptide of SEQ ID NO: 103.

Groups 68-91, claim(s) 11, in so far as it is drawn to an antibody that binds **any one** of the twenty-four isolated polypeptides recited in claim 8, classified in class 530, subclass 389.1, for example. For examples, the Invention of Group 68 consists of claim 11, only in so far as it encompasses an antibody that binds the isolated polypeptide of SEQ ID NO: 13; the Invention of Group 91 consists of

claim 11 only in so far as it encompasses an antibody that binds the isolated polypeptide of SEQ ID NO: 103.

Groups 92-115, claim(s) 12, in so far as it is drawn to a method of screening substances that bind a teneurin c-terminal associated peptide comprising incubating **any one** of the peptides of claim 8 with a test substance, classified in class 435, subclass 7.1, for example. For examples, the Invention of Group 92 consists of claim 12, only in so far as it encompasses screening for substances comprising incubating with the polypeptide of SEQ ID NO: 13; the Invention of Group 115 consists of claim 12, only in so far as it encompasses screening for substances comprising incubating with the polypeptide of SEQ ID NO: 103.

Groups 116-139, claim(s) 13-18, in so far as they are drawn to a method for identifying a compound that affects the activity or expression of teneurin c-terminal associated peptide comprising incubating **any one** of the peptides of claim 8 with a test substance, classified in class 435, subclass 7.21, for example. For examples, the Invention of Group 116 consists of claims 13-18, only in so far as they encompass the method comprising incubating with the polypeptide of SEQ ID NO: 13; the Invention of Group 139 consists of claims 13-18, only in so far as they encompass the method comprising incubating with the polypeptide of SEQ ID NO: 103.

Groups 140-163 claim(s) 19-20, in so far as they are drawn to a method of inhibiting cell proliferation comprising administering to a cell an effective amount of **any one** of the peptides of claim 8, classified in class 514, subclass 2, for example. For examples, the Invention of Group 140 consists of claims 19-20, only in so far as they encompass the method comprising administering the polypeptide of SEQ ID NO: 13; the Invention of Group 163 consists of claims 19-20, only in so far as they encompass the method comprising administering the polypeptide of SEQ ID NO: 103.

Groups 164-187, claim(s) 21, in so far as it is drawn to a method for detecting a condition comprising assaying for the presence of a nucleic acid molecule encoding **any one** of the teneurin c-terminal associated peptides of claim 8, classified in class 435, subclass 6, for example. For examples, the Invention of Group 164 consists of claim 21, only in so far as it encompasses the method comprising assaying for the presence of the nucleic acid molecule encoding SEQ ID NO: 13; the Invention of Group 187 consists of claim 21, only in so far as it encompasses the method comprising assaying for the presence of the nucleic acid molecule encoding SEQ ID NO: 103.

Groups 188-211, claim(s) 22-23, in so far as they are drawn to a method of treating a condition comprising administering to a cell or animal **any one** of the teneurin c-terminal associated peptides of claim 8, classified in class 424, subclass 9.1, for example. For examples, the Invention of Group 188 consists of

claims 22-23, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 13; the Invention of Group 211 consists of claims 22-23, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 103.

Groups 212-235, claim(s) 22-23, in so far as they are drawn to a method of treating a condition comprising administering to a cell or animal a nucleic acid molecule encoding any one of the teneurin c-terminal associated peptides of claim 8, classified in class 435, subclass 455, for example. For examples, the Invention of Group 212 consists of claims 22-23, only in so far as they encompass the method comprising administering a nucleic acid molecule encoding the isolated peptide of SEQ ID NO: 13; the Invention of Group 235 consists of claims 22-23, only in so far as they encompass the method comprising administering the nucleic acid molecule encoding the isolated peptide of SEQ ID NO: 103.

Groups 236-259, claim(s) 24, 28 and 29-30, in so far as they are drawn to a method of inducing an anxiogenic response comprising administering to a subject an effective amount of any one of the teneurin c-terminal associated peptides of claim 8, classified in class 424, subclass 9.1, for example. For examples, the Invention of Group 236 consists of claims 24, 28 and 29-30, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 13; the Invention of Group 259 consists of claims 24, 28

and 29-30, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 103.

Groups 260-283, claim(s) 25-26, in so far as they are drawn to methods of inhibiting an anxiogenic response comprising administering to a subject an effective amount of an inhibitor of any one of the teneurin c-terminal associated peptides of claim 8, classification unknown. For examples, the Invention of Group 260 consists of claims 25-26, only in so far as they encompass the method comprising administering an inhibitor of the isolated peptide of SEQ ID NO: 13; the Invention of Group 283 consists of claims 25-26, only in so far as they encompass the method comprising administering an inhibitor of the isolated peptide of SEQ ID NO: 103.

Groups 284-307, claim(s) 27, in so far as it is drawn to a method of inhibiting cell damage comprising administering an effective amount of any one of the teneurin c-terminal associated peptides of claim 8, classified in class 514, subclass 2, for example. For examples, the Invention of Group 284 consists of claim 27, only in so far as it encompasses the method comprising administering the isolated peptide of SEQ ID NO: 13; the Invention of Group 307 consists of claim 27, only in so far as it encompasses the method comprising administering the isolated peptide of SEQ ID NO: 103.

Groups 308-331, claim(s) 28, 29 and 31, in so far as they are drawn to a method of decreasing anxiety or stress response comprising administering an effective

amount of any one of the teneurin c-terminal associated peptides of claim 8, classified in class 514, subclass 2, for example. For examples, the Invention of Group 308 consists of claims 28, 29 and 31, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 13; the Invention of Group 331 consists of claims 28, 29 and 31, only in so far as they encompass the method comprising administering the isolated peptide of SEQ ID NO: 103.

Groups 332-355, claim(s) 33, in so far as it is drawn to a method of treating cancer comprising administering an effective amount of any one of the teneurin c-terminal associated peptides of claim 8, classified in class 514, subclass 2, for example. For examples, the Invention of Group 332 consists of claim 33, only in so far as it encompasses the method comprising administering the isolated peptide of SEQ ID NO: 13; the Invention of Group 355 consists of claim 33, only in so far as it encompasses the method comprising administering the isolated peptide of SEQ ID NO: 103.

2. Pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features"

shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As such, pursuant to 37 C.F.R. § 1.475 (b), the ISA/US considers that when an international or a national stage application containing claims to different categories of invention unity of invention exists if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The inventions of Groups 1 through 91 are drawn to structurally distinct nucleic acid molecules, polypeptides or antibodies. Proteins and nucleic acid sequences are materially distinct structures; proteins comprising of amino acids while nucleic acid molecules are comprised of nucleic acid bases. Proteins and nucleic acids have different methods and modes of use, for example proteins mediate cellular functions such as receptors, channels, intracellular signaling molecules or enzymatic reactions, whereas the functions of nucleic acid molecules are limited to the nucleus of the cell. Proteins and nucleic acid molecules, as claimed, do not encompass overlapping subject matter, are not interchangeable or substitutable in function or effect. Likewise,

antibodies are specialized protein structures that are structurally distinct and subserve distinct physiological functions from polypeptides. Structurally, antibodies are unique from antagonists and other proteins in that they are comprised of 4 specialized protein chains linked by disulphide bonds. The inventions Groups 92-355 are drawn to materially distinct methods that require structurally different materials, different active steps and/or have distinct outcomes or effects. Furthermore, many of these inventions have different patent classification categories and they do not fall into one of the combinations that the ISA/US considers as supporting unity of invention.

3. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Effective November 1,2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21,2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11,2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1,2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see:

http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a bona-fide reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within TWO MONTHS from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1,2007, the election must be filed within ONE MONTH or THIRTY DAYS, whichever is longer, from the

mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/SNM/

OLGA N. CHERNYSHEV
PRIMARY EXAMINER